

Remarks

Applicant believes that this amendment places the subject application in better condition for allowance and in so doing introduces no new issues. Therefore, entry of this Amendment, reconsideration of the application, and allowance of all claims pending herein is respectfully requested.

Claims 1-43 were originally presented in the subject application. Claims 29-43 have been withdrawn due to a previous restriction requirement. Independent claims 1 and 8 have been amended. Claims 1-28 remain in this case.

The Examiner's concerns are addressed separately below in the order raised in the outstanding Office Action. No new matter has been added.

Rejections under 35 U.S.C. §102(b)*Claims 1, 3, 8, 10, 15-17, 23-25 and 28*

Claims 1, 3, 8, 10, 15-17, 23-25 and 28 stand rejected under § 102(b) as anticipated by Howard III et al., U.S. Patent No. 5,654,803. Applicant respectfully traverses this rejection, to the extent that this rejection is deemed applicable to the currently amended independent claims.

As amended, independent claim 1, from which claim 3 depends, recites "determining that the test strip is misidentified in the event the one or more reagents are outside of the acceptable predetermined range." Support for this amendment may be found in the preamble of original claim 1, and in the specification at p. 8, lines 7-21. Similarly, amended independent claim 8, from which claim 10 depends, recites "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range." Support for this amendment may be found in the preamble of original claim 8, and in the specification at p. 8, lines 7-21.

Howard III et al. do not disclose using a reading from a test strip to detect the misidentification of the test strip. Instead, Howard III et al. disclose decoding the reading to determine the amount of blood on a test strip. "The decode reading is used to categorize the urine sample into one of three blood concentration categories: large blood concentration, medium blood concentration, or small blood concentration." (Howard III et al. col. 7 lines 57-

61).

Independent claim 15, from which claims 16, 17, 23-25 and 28 depend, recites in step (a) "marker fields reflecting light at different ranges of wavelengths from each other and from said test field in a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip." Howard III et al. do not disclose either marker fields or a coded sequence correlating to identifying information for a test strip.

Therefore, Howard III et al. do not anticipate claims 1, 3, 8, 10, 15-17, 23-25 and 28.

Rejections under 35 U.S.C. §102(e)

*Claims 1-3, 5, 7-10, 12, and 14*

Claims 1-3, 5, 7-10, 12, and 14 stand rejected under § 102(e) as anticipated by Corey et al., U.S. Patent No. 6,316,264. The invention disclosed by Corey et al., which only qualifies as prior art under § 102(e), and the claimed invention were, at the time the claimed invention was made, both subject to an obligation of assignment to the Bayer Corporation. Moreover, the instant application (and Corey et al.) has a priority date after November 29, 2000, and as such, the current language of § 103(c) is applicable. Therefore, under § 103(c), the Corey et al. reference should not be cited against the instant application.

In the alternative, Applicant respectfully traverses this rejection, to the extent that this rejection is deemed applicable to the currently amended independent claims. As discussed above, Corey et al. do not disclose the characteristic of determining whether a test strip is misidentified, and therefore do not anticipate claims 1-3, 5, 7-10, 12, and 14.

Rejections under 35 U.S.C. §103(a):

*Claims 4, 6, 11, 13, 18-22, and 26-27*

Claims 4, 6, 11, and 13 stand rejected as unpatentable over Corey et al.; claims 18-22 stand rejected as unpatentable over Howard III et al. in view of Corey et al.; and claims 26-27 stand rejected as unpatentable over Howard III et al. in view of Corey et al., and further in view of Poto et al., U.S. Patent No. 5,728,352. Under § 103(c), as discussed above, the Corey et al. reference should not be cited against the instant application. As such, Applicant requests

withdrawal of this rejection.

In the alternative, Applicant respectfully traverses these rejections, to the extent that these rejections are deemed applicable to the currently amended independent claims. It is well settled that in order to make a prima facie case of obviousness, the cited references must teach or suggest each and every element of the claims. MPEP § 2143.03. The cited references do not teach or suggest the characteristic of amended claim 1, from which claims 4 and 6 depend, of "determining that the test strip is misidentified;" or the similar characteristic of amended claim 8, from which claims 11 and 13 depend, of "determining that said test strip is misidentified." None of the cited references discloses this characteristic.

In addition, the cited references do not teach or suggest the characteristic of independent claim 15, from which claims 18-22 and 26-27 depend, of "a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip."

The Office Action does not indicate that the cited references disclose marker fields reflecting light in "a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip." Instead, the Office Action simply states that Howard III et al. teach "a coded sequence of wavelengths." (Office Action p.3, *see also* pp.8,9). However, Howard III et al. do not teach or suggest either marker fields or a coded sequence of wavelengths otherwise configured for the identification of a test strip. Instead, Howard III et al. disclose reagent pads 30 on a reagent strip 22, with "each reagent and reagent pad 30 being associated with a particular test to be performed." (Howard III et al. col. 3 lines 41-46). The Howard III et al. reagent pads 30 are therefore not marker fields suitable for use as identification fields.

A separate marker field for the identification of a test strip, for example the spectral identification marker field 504 disclosed in the application, is a significant structural difference from the Howard III et al. reagent strip. Also, as claimed, the reading means must be equipped to differentiate between the wavelengths at which the marker fields and the testing fields reflect. In contrast, the Howard III et al. machine is not configured for the identification of a test strip from the spectral reflectance of marker fields on the test strip. Corey et al. and Poto et al. also do

not disclose or suggest a coded sequence of ranges of wavelengths correlating to identification information for the test strip, or a machine configured to read such a coded sequence.

The cited references also show no recognition of the problem of accurate identification of test strips, and therefore do not suggest Applicant's claimed invention. The Howard III et al. disclosure is focused on the problem of miscategorizing blood concentration in a sample. (Howard III et al. col. 1, lines 46-48, 59-63). Corey et al. state that "the present invention is directed to a dry phase test strip that ensures proper alignment of the test strip in a detection apparatus, such as a spectrophotometer." (Corey et al. col. 3 lines 61-64). The Poto et al. disclosure is limited to a specific type of test strip and test strip reader, making it unnecessary to address the issue of misidentifying a test strip. "The present invention relates generally to a disposable electronic diagnostic instrument.... The diagnostic instrument is designed and calibrated specifically for use with diagnostic test strips supplied with the OTC cholesterol test kit for measuring and displaying the cholesterol level of a tested whole blood sample." (Poto et al. col. 1 lines 11-19). Therefore, the cited references do not teach or suggest marker fields configured to reflect a coded sequence of ranges of wavelengths correlating to identification information of a test strip.

### CONCLUSION

For at least each of the foregoing alternate reasons, Applicant respectfully requests reconsideration and allowance of the pending claims. Dependent claims 2-7, 8-14, and 16-28 are believed allowable for the same reasons as the independent claims from which they depend, as well as for their own additional limitations. Applicant therefore further submits that all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot.

This application is now believed to be in condition for allowance, and such action at an early date is respectfully requested. However, if any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the

Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0734** referencing Docket No. MSE #2620. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'RLS', followed by a horizontal line.

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